



International Dairy Foods Association

Milk Industry Foundation

National Cheese Institute

International Ice Cream Association

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Docket No. 02N-0276 - Registration of Food Facilities

To the Dockets Management Branch:

The International Dairy Foods Association (IDFA) is the Washington, D.C.-based organization representing the nation's dairy processing and manufacturing industries and their suppliers. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). Its 500-plus members range from large multinational corporations to single-plant operations, and represent more than 85% of the total volume of milk, cultured products, cheese, and ice cream and frozen desserts produced and marketed in the United States - an estimated \$70 billion a year industry.

IDFA strongly supports the overall concept and provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), and the Food and Drug Administration's (FDA) critical role and goal of ensuring the safety and wholesomeness of the American food supply and maintaining consumer confidence. IDFA offers the following comments regarding the FDA's proposed regulation on registration of food facilities published in the Federal Register on February 3, 2003.

The issues addressed in these comments are:

1. The volume of requested registration information.
2. FDA's interpretation of the term "food."
3. FDA's interpretation of the term "facility."
4. Data collection, techniques.
5. Protection of confidential business information.
6. Revising registrations.
7. Registration of temporary facilities.

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Issue #1 -Volume of requested registration information.

In the Bioterrorism Act, Congress states the regulation shall require the submission of information necessary to notify the Secretary of four elements: 1) the name of the facility, 2) the address of the facility, 3) the trade names under which the facility operates, and 4) when determined by the Secretary through guidance, the general food category.

While IDFA envisioned that FDA might need additional data not directly identified by Congress, we are concerned that FDA's broad approach may hinder FDA's ability to achieve its goals. The more data FDA collects, the more difficult the data will be able to be understand, search, and maintain

IDFA requests that FDA delete the request for all information characterized in the proposal as "optional," with two exceptions, sections 8 and 9. We especially believe FDA would delete sections 3, 4, 10, and 11a.

Section 8, is a necessary section and should be collected as applicable. We would concur with FDA that approximate dates of operation are the preferred choice given uncertainty that may arise for a host of reasons, especially relating to growing seasons.

With respect to section 9, FDA will in fact need some data elements by which FDA can extract a subset of the entire database to communicate with industry. The likely candidates for that segmentation are sections 9, 11 or 11a.

Section 11 is unworkable. A number of products appear to be covered under one of the 37 categories identified in section 11, but are in fact covered under another. For example, one would think that pudding would be captured under category 19, *gelatin, rennet, pudding mixes, or pie fillings*, when in fact, it appears pudding is covered under category 5, *bakery products, dough mixes or icings*. Given that a large quantity of fluid milk, a category 24 product is added to pudding mix, a category 19 product, one might think that the resultant pudding, like yogurt, belonged in category 24, *milk, butter, or dried milk products*, but it does not. Further, the heading for category 24, would seem to indicate that yogurt did not belong in category 24 either, as it is not milk, butter or a dried milk product, but despite that category heading, it does belong and the category is not limited to dry milk products. Given the anticipated confusion and uncertainty that will undoubtedly apply to section 11, IDFA believes section 11 cannot be used as FDA has proposed. This is especially true given the section 12 requirement that the respondent certify to the truth and accuracy of the information being provided without qualification.

While we agree that section 11a is an improved breakdown of food categories over section 11, it too suffers the same deficiencies described above. For example, a number of milk products in category 14, are also cultured, and could considered to be fermented products under category 12. Similarly, a dairy based dip containing fish could be a category 12, 14, or category 13 item. IDFA is certain that the flaws exhibited by these examples are undoubtedly found throughout any scheme that is based upon breaking food products down to categories.

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Given the certification requirements and the time that individuals will need to research and analyze the categories we would prefer to see the usage of the scheme devised in proposed section 9. With almost complete certainty, we feel that FDA and our member companies will not have to spend inordinate amounts of time considering which of the 11 boxes in this section apply to them and FDA will have a meaningful means of subcategorizing its database of food facilities in the event FDA needs to communicate to a certain segment.

We feel this is a better approach and less inclined to exclude wrongfully certain categories because either FDA, or the facility submitting a registration miscategorized a product under section 11 or 11a. Further, based upon our own past experiences it is difficult to understand when a circumstance applies to a milk, cheese or ice cream company, or any combination thereof. While not always the case, our experience would show that the broad based approach works well.

Finally, given our past experiences, we feel strongly that when a circumstance arises that warrants an alert being issued to food facilities, specificity will not be available and the only prudent approach will be to make a broad based announcement. Our conclusion is, therefore, that FDA's registrations should be segmented on the basis of the type of activity being performed at the facility, rather than the products being produced. This will have the further mutual benefit of limiting the need for constant updates to the FDA database as product lines are frequently changed.

With respect to section 4, IDFA does not believe the Bioterrorism Act requires this information. IDFA does, however, recognize that there may be circumstances under which it may be more sensible for FDA to contact a parent company rather than individual facilities. IDFA would suggest that those circumstances are embedded in a parent company's policies and procedures and that such determinations should dictate to whom government communications should be addressed. As such, we would be amenable to providing parent company information, but only if a parent company chooses to register all the facilities that are under its management and control. The logistics of a parent company doing so are further addressed in these comments under Issue #4.

With respect to the remaining sections, IDFA believes Section 1a is unnecessary. That information will be self evident based on the name of the country identified in the *country* field in Section 2. IDFA would also suggest using a drop down field for that information to preclude variants of the same country and misspellings.

After FDA has experienced managing the basic information necessary to meet the needs of the Bioterrorism Act, FDA can and perhaps should consider, through rulemaking, additional data elements. Given the very short timeframe for FDA to implement the regulation, it will be in everyone's best interest for FDA to focus on immediate needs to meet the October 12, 2003 final rule publication deadline.

Issue #2 - FDA 's interpretation of the term "food."

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For the purposes of the registration regulation under the Bioterrorism Act, FDA proposes to define the term "food" as it does in the Federal Food Drug and Cosmetic Act (FFDCA), Section 201(f). Section 201(f) states "*The term 'food' means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.*"

FDA also proposes to include examples of products considered food under 201(f) of the act. These examples include, but are not limited to: Fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food.

FDA should define food in a sensible manner that will result in an efficient and workable regulation. IDFA asserts that the proposed definition, that is, the acceptance of the previous definition of food is unworkable. Taken to its logical conclusion, this definition include not only those items traditionally understood as food, but also virtually all items that come into contact with a food during the processing or packaging, stretching the scope of the regulation beyond FDA's ability to enforce as well as expanding its reach so far as to undermine the intent and efficacy of the program the regulation intends to effect. For example, theoretically, trace molecular amounts of metals, or oxides of metal can migrate from stainless steel to a food product during food processing. Similarly, miniscule amounts of materials from conveyors, cutting boards, utensils, piping and in all likelihood millions of other items can also be transferred or migrate into a food during processing. The rule as proposed could cover virtually every material that ever contacts food.

As an alternative, IDFA urges FDA to adopt a risk based scheme. If the information being collected will not assist in protecting the safety and security of the food supply, it should not be collected because, in fact it will instead hinder rather than help.

As indicated in IDFA's separate comments filed in response to the proposed regulation on *Prior Notice of Imported Food*, FDA should focus accomplishing the goals of the Bioterrorism Act, without encumbering itself with unnecessary details competing for limited FDA resources. Therefore, the acid test should be to require registration for those food items, and facilities, that could be used to contaminate the food supply.

Since resources are finite, every dollar and minute FDA employees spend tracking unnecessary information are dollars and minutes that FDA could have used to protect the US food supply. IDFA emphatically encourages FDA to give utmost consideration to necessary elements, and eliminate anything not relevant and which will detract from meaningful consideration of where realistic and tangible risks lie.

Issue #3's - FDA's interpretation of the term "facility"

IDFA raised the issue of what constitutes a facility in the pre proposal comments filed in August 2002. In our comments, we pointed out that under other regulatory schemes adopted by other federal agencies, the term "facility" had been defined broadly. IDFA is

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encouraged by FDA's current proposal which is not unnecessarily restrictive, but we feel it could still be expanded for the benefit of FDA and the regulated community.

Under the current proposal, FDA would not require separate registrations for buildings that are contiguously located on the same property provided that they are owned or operated by the same management. Further, FDA has stated in a food industry meeting that the mere existence of a public road that bisects a contiguous piece of property would not destroy the continuity and result in unnecessary additional registrations.

IDFA would argue, however, that limiting the scope of a facility's boundaries to the property lines of a single piece of property is not a correct approach in all cases. In the dairy processing and, in all likelihood, many other food processing industries, there are a number of buildings that exist for the sole purpose of holding materials, such as packaging materials and sundries to be used in finished products or for holding finished products themselves. In many cases, these non-contiguous buildings are relatively close by and frequently are unmanned or minimally manned.

IDFA would urge FDA to permit these auxiliary buildings to be included in a facility's registration if they are located within the same town or municipality and are under the same management and control as the processing facility. A critical consideration in this issue is whether FDA could gain additional useful information by requiring a separate registration. In this situation identified here, the only additional useful information might be the address as in all likelihood the only additional personnel information would be name of a security guard, which is not an appropriate point of contact for FDA to utilize. In the event FDA feels that it must have those additional addresses in its database, FDA can include a line in its registration that requests those other street addresses that are included in the facility's registration.

Issue #4 - Data collection techniques

IDFA commends FDA for allowing flexibility in how a company registers its facilities. That is, FDA is correctly permitting corporate and regional headquarters personnel to register all facilities under their control while also providing flexibility by allowing for the delegation of that responsibility to the regulated facilities themselves. IDFA believes this flexibility will allow the burden and responsibility to be appropriately placed given the variety of corporate structures that exist in today's workplaces.

IDFA would, however, make a request that FDA allow for two additional options. One option would be to allow for the online pausing or holding of registrations in process. This would allow an individual to check additional facts without having to restart the process.

In addition, we would like to request that FDA support the processing of a multitude of facility registrations en masse by corporate or regional personnel. As alluded to in our comments under issue # 1, IDFA believes that a corporation should be able to designate a person or persons within the company to register the entire set of facilities within that corporation. We would suggest that when doing so, it would be most helpful if redundant

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data automatically flowed through from one record to another to eliminate retyping, which, has the added benefit of minimizing typographical errors.

Further, we would also like the option to allow external databases to be developed at the corporate or regional level and allow those databases to be uploaded online into FDA's database. We would like to make use of this option for the initial registration as well as subsequent updates. IDFA envisions that this can be technically achieved with many commonly available software packages. This will allow the regulated community to maintain and update its information independently and then periodically update it and upload it to the FDA system. One of the greatest benefits to the regulated community of using external databases is that it will allow for global search and replacements. This is particularly helpful when a company needs to reassign the designated contact person, change area codes or perform other one to one replacements or data maintenance tasks that would otherwise require having to page through countless online facility registrations and make the changes one at a time. For FDA, the benefit lies in the fact that by allowing these external databases, FDA will have better quality information and it will also be able to secure the information required for in proposed section 4.

Issue #5- Protection of confidential business information

IDFA and the regulated community are concerned about inappropriate distribution of sensitive information about facilities, personnel, activities and other information collected under this and the other Bioterrorism Act regulations. As FDA is well aware this regulation is being promulgated under a security act passed by Congress, not a community-right-to-know act. IDFA mentioned the differences in the comments we filed in August 2002 in response to FDA's request for pre-proposal information. We are pleased to learn that FDA shares our concern and has clarified that FDA intends to keep all the information gathered under this regulation confidential except that it will provide other local, state and federal agencies with relevant information on an as needed basis. IDFA is, however, particularly concerned with the subsequent re-distribution of any data furnished to those other agencies and the possibility that those other agencies could be subject to forced disclosure under the provisions of the federal Freedom of Information Act or a state equivalent. IDFA would encourage FDA's legal department to consider carefully this possibility and take whatever steps are necessary to prevent subsequent inappropriate disclosures.

Issue #6 - Revising Registrations

We understand that FDA is proposing that all changes to registrations be accomplished in 30 days or less from the time such change occurs. Should FDA choose to accept and act upon most of the suggestions provided for in these comments - that is a reduction of the requested data elements, we do not envision this requirement will be onerous. If, however, FDA continues its broad all encompassing strategy, we would assert that it would be appropriate for FDA to develop a two tiered hierarchy for accepting data changes. Items such as area code changes and any information that was optional should not need to be updated within 30 days. IDFA would suggest there are a host of other data items that should be second tiered as well should FDA follow the much referenced broad based plan.

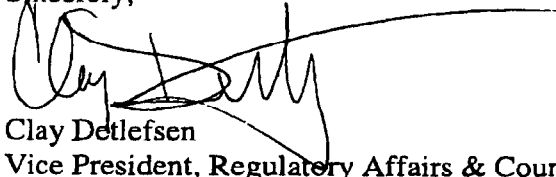
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Issue # 7 - Registration of temporary facilities

From time to time dairy processors need to lease temporary additional storage space. In many cases, the usage such storage space will be 90 days or less. Given the requirement to register and then submit changes, it would appear that almost as quickly as a company registered the temporary facility, it would be canceling registration. IDFA therefore would request that short duration leased storage spaces be exempted from the registration requirements. We would suggest limiting this to storage facilities, as the likelihood and severity of product tampering is considerably less than in a processing facility. Further, the short duration of the storage activity makes it unlikely to be a security risk because these facilities are not necessarily identified with a particular food company or even food for that matter.

As these comments indicate, IDFA's greatest of concern lies with the fact that it appears that FDA, with all good intentions, has taken a broad based approach to interpreting congressional intent. Given the vast uncertainties at this stage in the process, IDFA feels the broad based approach is risky, and urges FDA to pursue a strategy of accomplishing the immediate needs and pursuing additional helpful items in the future. With that said, IDFA commends FDA for the job it has done thus far and appreciates the opportunity to comment on the registration proposal. IDFA is willing to meet with FDA or answer any questions to help achieve these important objectives of this regulation.

Sincerely,



Clay Detlefsen
Vice President, Regulatory Affairs & Counsel



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Please see the following from Clay Detlefsen, Vice President and General Counsel, International Dairy Foods Association. Please let us know if we can provide further information.